NOTICE OF PROPOSED REGULATION ADOPTION

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute for Regenerative Medicine
Chapter 2

Date: November 21, 2008

Deadline for Submission of Written Comment: January 5, 2009 – 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Regulations: Exemption Petition for Lines Derived Prior to November 22, 2006.

Sections Affected:

The proposed action adopts section 100081 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and sections 125290.35, subdivisions (a), (b)(1), (2), (3), (4), (5) and (6); and 125290.40, subdivision (j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 125290.55, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in early 2005 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides $3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens Oversight Committee ("ICOC") is the 29-member governing board for the Institute. ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The Scientific and Medical Accountability Standards Working Group ("Standards Working Group" or "SWG") makes recommendations to the ICOC on scientific, medical and ethical standards pertaining to stem cell research the Institute funds. Specifically,

California Health and Safety Code section 125290.55 requires the Standards Working Group to: 1) recommend to the ICOC scientific, medical and ethical standards; 2) recommend to the ICOC standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with paragraph (2) of subdivision (b) of Section 125290.35, and to ensure compliance with patient privacy laws; 3) recommend to the ICOC modification of the standards described in numbers (1) and (2) as needed; 4) make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in numbers (1) and (2); and, 5) advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on an on-going basis on relevant ethical and regulatory issues.

CIRM regulations require hESC lines derived prior to November 22, 2006 – the date the MES regulations took effect – to (1) be recognized by an authorized authority or (2) conform to specific regulatory criteria. hESC lines that do not meet either standard are not eligible for use in CIRM-funded research.

On July 25, 2008, CIRM presented an example to the SWG of a scientifically significant hESC line derived before November 22, 2006, in accordance with the prevailing ethical standard of care at the time. The line, however, does not conform to the exact regulatory criteria set forth in the CIRM regulations. The MES regulations have the effect of applying requirements retroactively to hESC lines.

It was the sense of the SWG that for lines derived before the effective date of the regulations, there is a need for a "grandfathering" process to evaluate materials for use in CIRM-funded research. The proposed regulation creates a process that would allow use of such lines under certain circumstances. This evaluation process should include the following:

1. Consideration of the informed consent from the woman or couple in IVF (and no indication that original donor would not consent for research);

2. Consideration of documentation related to the approval of the donation protocol by an Institutional Review Board;

3. Consideration of compliance with prevailing ethical and legal standards in place at the time of derivation in the jurisdiction where the derivation was carried out;

4. Documentation of the scientific or medical significance of the hESC line.

The evaluation process would be initiated with a request to CIRM. Staff would review the request and make a recommendation to the ICOC. The ICOC would consider the request in a public meeting.

Technical, Theoretical or Empirical Studies, Reports or Documents:

A. Documents or Laws:

None.

B. Public Input:

Discussion and public input received at two public meetings conducted by the Standards Working Group on July 25, 2008, and the ICOC on August 12, 2008.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section "B" are available on CIRM's website, www.cirm.ca.gov under the "Meetings Transcripts" and "Meetings Minutes" links.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on January 5, 2009. Comments regarding this proposed action may also be transmitted via e-mail to mescomments@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than December 22, 2008.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The proposed amendments implement conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article

XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory action.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed action will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the proposed regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the proposed amendments to the regulations, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

Tamar Pachter, General Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9122

Questions on the substance of the proposed regulatory action may be directed to:

Geoff Lomax, Senior Officer for Medical and Ethical Standards
California Institute for Regenerative Medicine
(415) 396-9134

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact

person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at www.cirm.ca.gov.